

National Institutes of Health National Cancer Institute Bethesda, Maryland 20892

November 2, 1999

Barrett N. Fountos U.S. Department of Energy Office of International Health Programs, EH-63/270CC 19901 Germantown Road Germantown, MD 20874-1290

Dear Mr. Fountos:

Enclosed please find the Scientific and Management Progress Report for the time period 1 August 1999 through 31 October 1999 for the Chornobyl Research Program. Please feel free to contact me if you have any questions regarding this report.

Sincerely,

Terry L. Thomas, Ph.D.
Senior Staff Scientist

Chornobyl Research Unit

Radiation Epidemiology Branch, NCI

EPS, Room 7100

6120 Executive Boulevard

Rockville, MD 20852-7238

Phone: 301-594-7658



National Institutes of Health National Cancer Institute Bethesda, Maryland 20892

Chornobyl Research Program SCIENTIFIC AND MANAGEMENT PROGRESS REPORT 1 August 1999 to 31 October 1999

Submitted by:

Terry L. Thomas, Ph.D.

Date:

2 November, 1999

I. Progress on "Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and Ukraine (UkrAm Thyroid Project)

A. BelAm Thyroid Project

The study began in 1997 with the selection of individuals to be included in the study cohort from the file of thyroid dose measurements at the Institute of Biophysics in Moscow. The initial target cohort numbered 19,736 individuals. Numerous sources were used to trace subjects, and current addresses were located for 13,024. Invitations to participate in the study were sent to these subjects; second follow-up letters were sent to 7,805 individuals who did not respond to the first letter; and third follow-up letters were sent to 5,813 non-respondents to the second letter. These contacts resulted in 7,195 responses, 5,668 of whom agreed to come for screening. The remaining responses included refusals (1.4%), reports of subject's death (1.3%), subjects who had moved outside Belarus (6.3%), subjects who did not meet the age criteria for the study (0.5%), subjects serving in the army (8.2%), subjects in prison (1.1%), and duplicates (2.3%). As of this time, a total 5,135 individuals have been screened. Thyroid nodules were detected in 345 subjects, and newly diagnosed thyroid cancer was found in 19 subjects.

B. UkrAm Thyroid Project

The study in Ukraine began also in 1997 with the selection of 20,071 subjects to be included in the study cohort selected from the list of people with thyroid dosimetry. Current addresses for subjects were sought from numerous sources, and intensive tracing of about 4,000 difficult-to-locate subjects was conducted during the last quarter. Tracing efforts resulted in the location of 13,493 subjects. Of these, 7,387 were invited for screening, beginning in April 1998. As of 1 October 1999, a total of 3,866 subjects had been examined, about 600 of them during the last quarter. Eight newly diagnosed cases of thyroid cancer have been detected, two within the last quarter.

C. Other Progress

The NCI Chornobyl Oversight Panel had meetings in September and October to review status of the study. A list of immediate action items was distributed for discussion at

the September and October meetings. The list included such items as developing a plan for continual retraining of recruiters and interviewers, preparation of letters to send to participants after screening, streamlining data collection forms, evaluating mechanisms to increase the number of people screened each year, and other issues. Work on several of the items has been completed, while other items are currently being addressed. The list will be continuously updated with new items and items will be dropped as they are completed.

Bi-national Advisory Groups, established to provide scientific advice to project directors, had their first meetings October 11-12 (Belarus) and October 14-15 (Ukraine). The meetings were attended by project investigators from the respective countries as well as scientists from the U.S. working on the projects. Each Group recognized the importance of the studies, and was generally supportive of the proposed protocol modifications. Reports containing specific advice will be submitted by the Adivsory Group Chairs.

Revised power calculations indicated that a cohort of approximately 12,000 subjects from each country is necessary to achieve reasonable statistical power. Plans have been drafted by investigators in Belarus and Ukraine for achieving the desired cohort size by the end of the year 2000 and will be discussed at an upcoming joint meeting.

A joint meeting of Belarussian, Ukrainian, and American investigators is planned for 8-10 November 1999 to review the progress of both studies and to discuss numerous issues including: strategies for improving response rates, strategies for contacting and recruiting subjects, screening procedures, frequency of re-screening, standardizing the dosimetry questionnaires, collaboration between Belarussian and Ukrainian investigators, and other issues.

II. Progress on "Study of Leukemia, Lymphoma, and Related Disorders in Ukrainian Clean-up Workers Following the Chornobyl Accident"

A Phase 1 feasibility study began in November 1997 and will be completed in December 1999. The research protocol listed 30 specific tasks to be completed during Phase 1, including an investigation of sources from which a study cohort could be drawn, identification, location, and interviewing a representative sample of clean-up workers. The Chornobyl State Registry, a computerized data base of liquidators and other individuals affected by the Chornobyl accident was considered to be a usable source of a large cohort; however, a considerable number of workers, primarily those who were in the military at the time of the accident, were not entered into the Registry. Completeness of case ascertainment was investigated in one Oblast, and diagnostic validity of leukemia cases was evaluated in a sample from the entire study area. The pilot work on dosimetry included an investigation of all available information on tasks performed by cleanup workers and on their doses received during cleanup, and the development and testing of several new dose reconstruction methods.

A draft of the Phase 1 study report dated 11 October 1999 indicated that all tasks except for one were completed successfully. A meeting of the American members of the Leukemia Working Group was held on 19 October 1999 to discuss the draft Phase 1 report and make recommendations regarding future work. The Working Group recommended that

Page 3 -[Chornobyl Research Program - 02 November 1999]

plans for the first year of Phase 2 should be focused on reducing uncertainties and eliminating problems encountered in Phase 1, including the following: (a) obtain access to additional files of workers in order to establish a cohort with a wider range of doses; (b) determine whether clean-up workers can be located in geographic areas other than the one in the pilot study; (c) further investigate the completeness of ascertainment of leukemia cases; and (d) improve the strategy for estimating individual doses to reduce uncertainty. A meeting of the joint Ukrainian-American Leukemia Working Group is scheduled for November 15-16, 1999 to review the status of the pilot study and discuss recommendations for future work.